

the specification, thus properly claiming priority to the prior application under 35 U.S.C. § 119 (e). Also, the specification has been amended on page 7 to give the accession numbers for the deposits to GenBank already referenced.

5        Claim 11 has been amended to include a space between Nit1 and protein, thereby addressing the objection raised to this Claim. Additionally, Claims 13 to 16 have been canceled without prejudice. The Applicant reserves the right to prosecute, in one or more patent applications, the canceled claims and any other claims supported by the  
10 specification.

The amendment to Claim 11 finds support in the application, as originally filed. No new matter has been added. Claims 1 to 3 and 10 to 11 are currently pending in the present application.

In the non-final Office Action mailed September 27, 2000, the  
15 Examiner rejected Claims 1 to 3, 10 to 11, and 13 to 16 under 35 U. S. C. §112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner rejected Claims 1 to 3  
20 and Claims 10 to 11 under 35 U. S. C. §112 for failure to enable any person skilled in the art to make the invention commensurate in scope with these. Claims 13 to 16 were rejected under 35 U. S. C. §112 as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with  
25 which it is most nearly connected, to make and/or use the invention.

Additionally, the Examiner rejected Claims 1 to 3, 10 to 11, and 13 to 16 under 35 U. S. C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner has rejected Claims 1 and 10  
30 under 35 U.S.C. §102(b) as being anticipated by Hillebrand et al. (May 8, 1996) Gene, Vol. 170 (2): 197-200. No claim has been allowed.

**Rejection of Claims 1 to 3 and 10 to 11**  
**under 35 U.S.C. §112, first paragraph**

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The Examiner has rejected Claims 1 to 3 and 10 to 11 under 35 U.S.C. §112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner alleges that the *NIT1* gene elected for examination is deemed to be an incomplete cDNA and the cDNAs that correspond to SEQ ID NO:1 are not full-length. The Applicant respectfully disagrees.

Full-length human and murine cDNAs were obtained according to the method described in detail beginning at page 12, line 13. A full-length human protein sequence and a full-length mouse protein sequence were obtained and are shown in **Fig. 1**. (page 12, lines 15-17). Moreover, murine and human clones containing the *NIT1* genes were obtained by screening genomic libraries, and the human and murine *NIT1* genomic regions were completely sequenced. (page 12, lines 24-31). The results are shown in **Fig. 3A**. Additionally, the specification has been amended on page 7, line 6 to include a reference to the specific accession numbers of the GenBank deposits referenced in the application as originally filed. These deposits include full-length cDNAs. Furthermore, Applicant has defined the conserved regions of the genus in **Fig. 1** (see **Fig. 1** and description, page 5, lines 12-15, and **Fig. 6**, with description on page 6, lines 4-5). Thus, Applicant's description, including the originally filed figures and specification, adequately describe the scope of the claimed genus, including full-length genes.

30 It is the Applicant's belief that claims 1 to 3 and 10 to 11 are supported by sufficient written description, as defined by the first paragraph of 35 U.S.C. §112. The Applicant has canceled without

prejudice Claims 13 to 16. Therefore, the Applicant respectfully requests the withdrawal of the rejection of Claims 1 to 3, 10 to 11, and 13 to 16 under 35 U.S.C. §112, first paragraph.

5      **Rejection of Claims 1 to 3 and 10 to 11 under 35 U.S.C. §112, first paragraph**

The Examiner has also rejected Claims 1 to 3 and 10 to 11 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner 10 alleges that the application is enabling for an isolated cDNA of a plant nitrilase *NIT1* but not for any and all nitrilase DNA nor for any isolated nucleic acid of less than 100 kb comprising a nucleotide sequence encoding a Nit1 protein. The Examiner contends that the specification fails to teach or provide parameters, mechanistic classes, or classes of 15 nitrilase domains for which one of skill in the art could reasonably predict that the *NIT1* gene encodes a functional protein which exists in any species.

The Applicant respectfully disagrees with Examiner's contention. In **Fig. 1**, Applicant demonstrates the identities and similarities in the 20 sequence of human, murine, *D. melanogaster*, and *C. elegans* Nit1 proteins. **Fig. 6** shows the highly conserved sequence of human, murine, *D. melanogaster*, and *C. elegans* *NIT1* genes. While human and mouse *NIT1* genes are members of a larger family of genes that is not fully characterized, *NIT1* genes have been fully characterized in the present 25 invention. Full-length human and murine cDNAs were obtained, and the human and murine *NIT1* genomic regions were completely sequenced. Although there is some homology between the larger uncharacterized gene family (of which *NIT1* is but a part) and the plant and bacterial nitrilases, *NIT1* is much more closely related to *FHIT* (page 2, lines 17-21). *Fhit* 30 occurs in a fusion protein, Nit-Fhit, in lower invertebrate animals, but *FHIT* and *NIT1* are separate genes in mammalian cells. (page 3, lines 26-29). Thus, the specification provides adequate guidance as to the location

and conserved sequence of *NIT1* genes and the nucleic acids encoding the *NIT1* genes across species.

It is the Applicants' belief that claims 1 to 3 and 10 to 11 are enabled, as defined by the first paragraph of 35 U.S.C. §112, and the  
5 Applicants respectfully request the withdrawal of the rejection of Claims 1 to 3, and 10 to 11 under 35 U.S.C. §112, first paragraph.

**Rejection of Claims 1, 10 and 11 under 35 U.S.C. §112,  
second paragraph**

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The Examiner has rejected Claims 1, 10 and 11 for being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The *NIT1* gene is identified in **Fig. 6** and is the same as NITD. Therefore, it is the Applicants' belief  
15 that claims 1, 10 and 11 are not indefinite, as defined by the second paragraph of 35 U.S.C. §112, and the Applicants respectfully request the withdrawal of the rejection of Claims 1, 10, and 11 under 35 U.S.C. §112, second paragraph.

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**Rejection of Claims 13 to 16 under 35 U.S.C. § 112,  
first paragraph and second paragraph**

The rejection of Claims 13 to 16 under 35 U.S.C. § 112 is moot in  
25 light of Applicant's cancellation of these claims without prejudice.

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**Rejection of Claims 1 and 10 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 1 and 10 under §102(b) as being anticipated by Hillebrand et al. The Examiner states that Hillebrand discloses “a full-length genomic clone encoding the complete cluster of the *At* nitrilases.” Although there is some homology between plant and 5 bacterial nitrilases on the one hand and the overall gene family of which *NIT1* is a member, *NIT1* genes are distinct from the nitrilases. *NIT1* genes have a much closer relationship to *FHIT*. Thus, Hillebrand’s description is not of *NIT1*, but of a less closely related nitrilase.

10 In summary, the teachings in the Hillebrand reference fail to anticipate the claimed invention. Hillebrand does not disclose a *NIT1* gene that is closely related to the genes of the present application.

15 It is the Applicants’ belief that Claims 1 and 10 are not anticipated by the Hillebrand et al. reference, as defined by 35 U.S.C. §102(b), and the Applicants respectfully request that the Examiner withdraw this rejection of Claims 1 and 10 under 35 U.S.C. §102(b).

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Thus, it is the Applicants' belief that claims 1 to 3 and 10 to 11 are enabled, definite, and novel and that Applicant had possession of the claimed invention at the time the application was filed. Prompt consideration and allowance of Claims 1 to 3 and 10 to 11 are earnestly  
5 solicited.

Should the Examiner determine that any further action is necessary to place this application into even better form, she is encouraged to telephone the Applicants' undersigned representative at the number listed below.

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3/27/2001  
Date

BY:

Respectfully submitted,

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